Risk factors for surgical failure after posterior intravaginal slingplasty: a case series

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Running Title: Posterior intravaginal slingplasty

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Condensation

Procidentia is a significant risk factor for surgical failure of posterior intravaginal slingplasty.
Abstract

Objective: The goal of this study was to analyze the potential risk factors of surgical failure after posterior intravaginal slingplasty for uterine or vaginal vault prolapse.

Study design: Women with symptomatic uterine or vaginal vault prolapse that extended to or beyond the introitus were eligible for inclusion. Each woman underwent a detailed history taking and a vaginal examination for staging of pelvic organ prolapse before treatment. Follow-up evaluations were at 3, 6, 9, 12, 18, 24, and 30 months after the operation. Surgical failure is defined as the presence of symptomatic uterine or vaginal vault prolapse \( \geq \) stage 2 (higher than 0, at the hymen) after posterior intravaginal slingplasty.

Results: The surgical failure rate (8/61) following posterior intravaginal slingplasty was 13.1%. Using univariable logistic regression, C or D point stage IV before surgery was significantly associated with surgical failure of posterior intravaginal slingplasty for uterine or vaginal vault prolapse. Complications (11/61 = 18%) included vaginal erosion (9.8%), blood loss over 500 ml (4.9%), and perineal pain (3.3%).

Conclusion: Procidentia is a significant risk factor for surgical failure of posterior intravaginal slingplasty, and therefore this procedure should never be used alone in patients with complete uterine or vaginal vault prolapse.
Keywords: Posterior intravaginal slingplasty; Uterine prolapse; Vaginal vault prolapse; Procidentia; Uterosacral ligament
Introduction

Pelvic organ prolapse (POP) is a common gynecological problem [1]. As life expectancy increases, significantly greater number of women will present with POP requiring surgical intervention. Currently, the lifetime risk of undergoing prolapse or continence surgery in the USA is one in 11, and up to 30% of patients will require repeat prolapse surgery [2,3].

Uterine or vaginal vault prolapse is thought to be due to defects in the integrity of the uterosacral-cardinal complex. These defects have been described as a general weakness of the ligament complex or as specific tears at various sites along the ligament [4]. Surgical treatment of uterine or vaginal vault prolapse has improved with use of the posterior intravaginal slingplasty (IVS, infracoccygeal sacropexy) technique, which reinforces the uterosacral-cardinal ligament complex to suspend the cervix or vaginal vault in a tension-free manner [5,6]. Success rates of posterior IVS for uterine or vaginal vault prolapse vary from 37% to 97.9% [5-12].

An exploration of the potential risk factors for surgical failure following posterior IVS was therefore thought to be of interest. The purpose of this study was to analyze the potential risk factors of surgical failure following posterior IVS. This information could be useful for the prevention of repeat prolapse surgery following posterior IVS.
Materials and methods

Between May 2004 and January 2007, women with pelvic floor disorders who attended the Urogynaecology Units at the China Medical University Hospital in Taichung were considered for the study. Women with symptomatic uterine or vaginal vault prolapse that extended to or beyond the introitus were eligible for inclusion. Only women who met the following criteria were excluded: (1) isolated cystocele; (2) stage 1 prolapse; (3) rectal prolapse; and (4) intestinal inflammatory disease. This study was approved by our institutional review board, and written informed consent was obtained from all of the women who participated in this study.

Detailed history takings and examinations were undertaken. All subjects were examined in a 45° semi-upright position with an empty bladder in a birthing chair during maximum Valsalva maneuver for staging of POP according to the criteria of the International Continence Society (ICS) [13,14]. All examinations were performed by a senior gynecologist.

The surgical procedure was carried out, under general anesthesia, according to the methods described by Petros [5,15]. The IVS Tunneler with the original multifilament tape (Tyco Healthcare, Norwalk, CT, USA) was used in all case. Key points of the operation include two small perineal incisions approximately 3 cm laterally and below the anus, insertion of the tape with a special designed tunneler,
and passage of the tunneler through the ischiorectal fossae and the iliococcygeus muscle below the sacrospinous ligament to reach a vaginal incision just below the cervix or vaginal vault [15]. Associated procedures were anterior and posterior colporrhaphy, hysterectomy, anti-incontinence surgery, and mesh augmentation (Gynemesh; Gynecare, Ethicon, rue Camille Desmoulins, France) [16-19]. Treatment outcomes were evaluated after 3, 6, 9, 12, 18, 24, and 30 months. All procedures were done by a senior gynecologist. Surgical failure (anatomic recurrence) is defined as the presence of symptomatic uterine or vaginal vault prolapse ≥ stage 2 (higher than 0, at the hymen) identified by two senior gynecologists on vaginal examination [13,14,20]. The follow-up period after posterior IVS for uterine or vaginal vault prolapse was 30 months.

Mann–Whitney test (Wilcoxon rank-sum test) and chi-square test were used for nonparametric ordinal and nonparametric categorical variables, respectively. To assess any association of surgical experience with the technique and surgical failure, a two-level ordinal variable based on cases was ranked by case number. When the assumption of the chi-square test was violated (i.e., when more than one cell had an expected count of less than 1, or more than 20% of the cells had an expected count of less than 5), the Fisher’s exact test was used. A logistic regression model and odds ratios (with 95 percent confidence intervals) were used to assess the independent
prognostic value of the variables associated with surgical failure. When variables have a $p$ value < 0.2 on univariate analysis, the variables will entry into the model of multivariable logistic regression. The success rates (defined as the absence of surgical failure) of subgroups were plotted on a life table. The log rank test was then used to compare the success distributions over time between groups. All statistical tests were two-sided. A $p$ value less than 0.05 was considered statistically significant. All of the calculations were performed by the Statistical Package for Social Sciences (SPSS for Windows, release 8.0, SPSS Inc, Chicago, IL, USA).
Results

A total of 65 consecutive patients underwent posterior IVS for treatment of uterine or vaginal vault prolapse. Of these patients, four were excluded from the analysis because they were lost to follow-up. Thus, 61 patients are included in the study. The patients’ mean age was 59.3 years (range, 32-76 years), and median parity was 4 (range 1-8). The surgical failure rate (8/61) was 13.1% during the 30-month follow-up period. After analyzing the influences of 11 factors on treatment outcome of posterior IVS (Table 1), C or D point before surgery was significantly associated with surgical failure of posterior IVS for uterine or vaginal vault prolapse.

Univariable logistic regression revealed that C or D point stage IV before surgery was significantly associated with surgical failure of posterior IVS for uterine or vaginal vault prolapse (Table 2). For surgical failure after posterior IVS, women with the presence of C or D point stage IV before surgery were 10.25 times (95% confidence interval: 1.83-57.51) more at risk than women with the presence of C or D point stage II before surgery ($p < 0.05$). However, no other variables belong to the model of multivariable logistic regression by the criterion (i.e., when variables have a $p$ value $< 0.2$ on univariate analysis).

Posterior IVS successfully controlled symptomatic uterine or vaginal vault prolapse (≧ stage 2) in many patients at the start of the study, but the success rate
gradually declined (Fig. 1). All patients were free of symptomatic uterine or vaginal vault prolapse \( \geq \) stage 2). When the patients were classified into three groups according to C or D point before surgery (the stage II group = women with the presence of C or D point stage II before surgery; the stage III group = women with the presence of C or D point stage III before surgery; the stage IV group = women with the presence of C or D point stage IV before surgery), the success rate during the 30-month follow-up differed significantly between the groups (Fig. 1).

Recurrence (surgical failure of posterior IVS for uterine or vaginal vault prolapse) was diagnosed after 2 year of surgery in one patient, in three patients from 12 to 18 months after surgery, and in four patients from 3 to 6 months after surgery. Symptoms of recurrence included vaginal bulging–discomfort (4), persistent vaginal discharge (1), voiding difficulty (1), tenesmus (1), and dyspareunia (1). Vaginal examination of patients with recurrence revealed uterine or vaginal vault prolapse stage II in six patients and stage III in two patients. One patient asked for conservative treatment with pessary. All of the other patients with recurrence were treated surgically. Complications occurred in 11 patients (18%). Complications included vaginal erosion [defined as the presence of foreign material (IVS tape) within the posterior vagina after vaginal wound healing] (9.8%), blood loss over 500 ml (4.9%), and perineal pain (3.3%).
Discussion

A new daycare method for repair of uterine or vaginal vault prolapse based on the integral theory, the posterior IVS (infracoccygeal sacropexy), was reported in 1997 by Petros [15]. There have been few studies of the risk factors associated with surgical failure after posterior IVS slingplasty for uterine or vaginal vault prolapse. In the present study, the surgical failure rate is 13.1%, which is compatible with the 2.1% to 63% reported in the literature [5-12].

The gynecologist faces a difficult challenge in the management of uterine or vaginal vault prolapse [21]. The pathological cause of procidentia is loss of the integrity of the uterosacral-cardinal ligament complex and weakening the pelvic diaphragm, allowing eversion of the entire vagina [11,22]. The present study shows that women with the presence of C or D point stage IV before surgery, which represents eversion of the entire vagina, are a significant risk factor for recurrent uterine or vaginal vault prolapse after posterior IVS. For surgical failure after posterior IVS, women with the presence of C or D point stage IV before surgery were 10.25 times more at risk than women with the presence of C or D point stage II before surgery. The success rate during the 30-month follow-up decreased significantly in women with the presence of C or D point stage IV before surgery. This finding is very similar to that report by Jordaan et al. [8]. Our data suggest that the posterior IVS will
not reinforce the uterosacral-cardinal ligament complex to suspend the cervix or vaginal vault in a tension-free manner day after day. The posterior IVS supports only the uterosacral ligaments. The uterus, however, is supported not only by the uterosacral ligaments, but also by the cardinal ligaments. The posterior IVS does not address the cardinal ligaments, nor does an anterior vaginal repair [23].

Vaginal bulging–discomfort (50%) in four patients was the most common symptom of recurrence. Vaginal examination of patients with recurrence revealed uterine prolapse stage III in two patients, all of whom were treated surgically. Vaginal erosion (9.8%) in 6 patients, who were managed conservatively or with minor surgical intervention, was the most common postoperative complication. This result is comparable with previous studies [5,10]. The mechanism by which vaginal erosion occurs following multifilament tape is still poorly understood. It is reasonable to assume that vaginal erosion is caused by multiple factors, such as poor incorporation, wound infection, impaired wound healing, and excessive foreign body reaction (mesh augmentation) [24]. Three patients (4.9%), all of whom were treated conservatively, had had increased bleeding (blood loss over 500 ml) during operation.

The frequency estimation analysis revealed that women with the presence of C or D point stage IV before surgery were more prevalent in surgical failure (75%) than in surgical success (22.6%). The $p$ value of the Fisher’s exact test was about 0.1% with a
power greater than 87%. Furthermore, the present study shows that the concomitant use of other surgical procedures during primary surgery e.g. hysterectomy or mesh augmentation technique was not significantly associated with surgical failure of posterior IVS for uterine or vaginal vault prolapse. The sample size, however, was relatively small, and our negative results may represent false-negative findings. A larger well designed study is needed to confirm this association. Also, variables that might predict failure are not available such as: work that requires heavy lifting, chronic constipation, and chronic asthma/cough, etc. Further study evaluating functional outcome with particular emphasis on quality of life is warranted.

In conclusion, the results of our study suggest that procidentia is a significant risk factor for surgical failure of posterior IVS. We should hesitate to use posterior IVS as an alternative surgery in women with procidentia, despite recurrence is well in accordance with other surgical procedures for uterine or vaginal vault prolapse [3, 25-27]. Thus posterior IVS will be considered for the treatment of women with symptomatic moderate uterine or vaginal vault prolapse.
Acknowledgements

The authors would like to thank the China Medical University Hospital for financially supporting this research under Contract DMR-99-090.
Disclosure of interests

The authors do not have any conflicts of interest.
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Table 1 Univariate analysis of clinical features of 61 patients with uterine or vaginal vault prolapse undergoing posterior intravaginal slingplasty

<table>
<thead>
<tr>
<th>Variables</th>
<th>Success (n = 53)</th>
<th>Failure (n = 8)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>59.2 ± 10.6</td>
<td>56.1 ± 14.1</td>
<td>0.474^a</td>
</tr>
<tr>
<td>Parity (median)</td>
<td>4 (1-7)</td>
<td>4 (1-8)</td>
<td>0.584^a</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>23.8 ± 2.8</td>
<td>23.9 ± 3.0</td>
<td>0.957^a</td>
</tr>
<tr>
<td>Menopause</td>
<td>38 (71.7)</td>
<td>4 (50)</td>
<td>0.241^b</td>
</tr>
<tr>
<td>Previous reconstructive pelvic floor surgery</td>
<td>9 (17)</td>
<td>0 (0)</td>
<td>0.591^b</td>
</tr>
<tr>
<td>Concomitant surgery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>7 (13.2)</td>
<td>1 (12.5)</td>
<td>1^b</td>
</tr>
<tr>
<td>Anti-incontinence surgery</td>
<td></td>
<td></td>
<td>0.219^b</td>
</tr>
<tr>
<td>without</td>
<td>11 (20.8)</td>
<td>4 (50)</td>
<td></td>
</tr>
<tr>
<td>IVS^c</td>
<td>10 (18.9)</td>
<td>1 (12.5)</td>
<td></td>
</tr>
<tr>
<td>TVT-O^d</td>
<td>32 (60.4)</td>
<td>3 (37.5)</td>
<td></td>
</tr>
<tr>
<td>Anterior and posterior colporrhaphy</td>
<td>16 (30.2)</td>
<td>4 (50)</td>
<td>0.420^b</td>
</tr>
<tr>
<td>Mesh augmentation</td>
<td></td>
<td></td>
<td>0.330^b</td>
</tr>
<tr>
<td>without</td>
<td>16 (30.2)</td>
<td>4 (50)</td>
<td></td>
</tr>
<tr>
<td>none secure^e</td>
<td>4 (7.5)</td>
<td>1 (12.5)</td>
<td></td>
</tr>
<tr>
<td>secure^f</td>
<td>33 (62.3)</td>
<td>3 (37.5)</td>
<td></td>
</tr>
<tr>
<td>C^g or D^h point before surgery</td>
<td></td>
<td></td>
<td>0.001^b</td>
</tr>
<tr>
<td>Stage II</td>
<td>31 (58.5)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Stage III</td>
<td>10 (18.9)</td>
<td>2 (25)</td>
<td></td>
</tr>
<tr>
<td>Stage IV</td>
<td>12 (22.6)</td>
<td>6 (75)</td>
<td></td>
</tr>
<tr>
<td>Surgical experience</td>
<td></td>
<td></td>
<td>1^b</td>
</tr>
<tr>
<td>1 — 30</td>
<td>26 (49.1)</td>
<td>4 (50)</td>
<td></td>
</tr>
<tr>
<td>□ ≥ 31</td>
<td>27 (50.9)</td>
<td>4 (50)</td>
<td></td>
</tr>
</tbody>
</table>

Values are mean ± standard deviation.
^aMann–Whitney test. ^bFisher’s exact test.
^cIVS: intravaginal slingplasty. ^dTVT-O: inside out transobturator vaginal tape.
^enone secure: the use of mesh via transvaginal route for treating anterior and posterior vaginal prolapse [19].
^fsecure: 1) the use of mesh via transobturator route for treating anterior vaginal prolapse; and 2) the use of mesh with anchoring arms in combination with posterior intravaginal slingplasty for treating posterior vaginal prolapse.
^gC point: cervix in pelvic organ prolapse quantification (POP-Q) system.
^hD point: posterior vaginal fornix in POP-Q system.
**Table 2** Univariate logistic regression of risk factors associated with surgical failure of posterior intravaginal slingplasty for uterine or vaginal vault prolapse

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>C(^a) or D(^b) point before surgery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage II</td>
<td>1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage III</td>
<td>1.43</td>
<td>0.25-8.18</td>
<td>0.6854</td>
</tr>
<tr>
<td>Stage IV</td>
<td>10.25</td>
<td>1.83-57.51</td>
<td>0.0082</td>
</tr>
</tbody>
</table>

CI denotes confidence interval.

\(^a\)C point : cervix in pelvic organ prolapse quantification (POP-Q) system.

\(^b\)D point : posterior vaginal fornix in POP-Q system.
Fig. 1 Survival curve of posterior intravaginal slingplasty with respect to C or D point at before operation in all patients during the 30-month follow-up period. Asterisk: Success indicates the absence of treatment failure; therefore, all groups had a 100% success rate at the start of the study. Stage II = the C or D point stage II at before operation group; stage III = the C or D point stage III at before operation group; stage IV = the C or D point stage IV at before operation group, where n = 61, log-rank test, $\chi^2 = 11.78$, df = 2 and $p = 0.0028$. 